

Scottish Medicines Consortium (SMC) Patient and Public Involvement Two Years On - A Progress Report

1. Background:

This paper describes a journey; a journey which is still in progress; a journey where we have and will continue to encounter difficulties but in which we build new bridges and, indeed, new motorways if necessary in order to reach our goal.

1.1 The past

A generation ago most patients adopted what would now be seen as a passive role in the provision of their healthcare. They coupled this with faith in the motives and competencies of those providing care.

1.2 The present

Today, by comparison, many patients expect to be involved in their own healthcare decisions; local communities expect to be consulted in respect of care provision in their locality; and the general public expect to be involved in healthcare policy decisions affecting Scotland.

1.3 Central initiatives: local actions

A modern NHS is committed to patient, carer and public involvement and active partnerships between service providers and service users.

- 'Our National Health' (2000) referred to the need to, 'give patients a stronger voice' and emphasised the need for information in order for patients and members of the public to become active partners in healthcare.
- This theme is continued throughout a series of publications including 'Patient Focus and Public Involvement' (2002) in which service ambitions are described as, 'A service where individuals', groups and communities are involved in improving the quality of care, in influencing priorities and in planning services.'
- 'Partnership for Care (2003) states, 'Understanding the wants and needs of patients ... will lead to more effective and high quality healthcare, and must be a core activity of the health service. It means developing a genuinely responsible health service by seeking input and feedback from patients as a key part of developing services and improving quality.'

- Quality Improvement Scotland (QIS) Generic Clinical Governance Standards; the Performance Assessment Framework (Section 5); and Clinical Incidents and Other Risks Indemnity Scheme (CNORIS) assessments all place high value upon i) involvement; ii) information; iii) responsiveness; and iv) building capacity and communications.

2. Lay membership versus patient and public involvement

2.1 From the outset, Ms Helen Tyrrell and Mrs Wendy Nganasurian were appointed to SMC to provide a lay perspective. Both had backgrounds in healthcare, the voluntary health sector and in patient and public engagement.

2.2 The role of lay member was never made explicit but the lay members themselves decided that wider involvement was a necessity if they themselves were not to be little more than tokenistic patient representation and at the inaugural meeting in October 2001 wider patient and public involvement was raised. The lay members were charged with presentation at the November meeting of a paper focusing upon the various issues, potential difficulties and solutions. That paper stated,

‘The key to achieving successful public involvement is both to effect and maintain a culture of openness and the provision of adequate resources to facilitate active, well-informed involvement’.

3. A team effort and total ‘sign-up’

3.1 In August 2002 an informal, emerging subgroup of SMC was formalised to carry forward the work of patient and public involvement. Ms Tyrrell and Mrs Nganasurian (chair) were joined by Ms Moira Howie, Healthcare Development Manager Association of British Pharmaceutical Industries (ABPI); and Ms Angela Timoney, Specialist in Pharmaceutical Public Health, NHS Tayside, and supported administratively by Mrs Jill Mitchell, SMC Secretariat.

3.2 Much of the success of SMC’s public involvement strategy lies within the constructive and complementary relationships between Patient and Public Involvement Group (PAPIG) members. Each member brings complementary yet diverse expertise and network links to the group whilst sharing an unfaltering commitment to public involvement. PAPIG meets after SMC on alternate months and normally concludes its business within 45 minutes.

3.3 There was no formal way of keeping other members of SMC updated on activities in the area of public involvement and, indeed, PAPIG could have been seen as ‘ploughing a lonely furrow’. Therefore, the group now feeds back to SMC verbally one month and as a written update the next. This process ensures that any member of SMC who is unable to be present does not miss out on the opportunity to be appraised of what is happening on the public involvement front and to contribute his/her views.

3.4 It is essential that patient and public involvement is not seen as solely the responsibility of PAPIG but is embraced by the wider membership. Members of SMC outwith PAPIG have shown their support for the group through both solicited and unsolicited feedback and through attendance at PAPIG meetings/events to which they

have an open invitation. Within SMC the culture is fully supportive of public involvement. Patient and Public Involvement has moved to a more prominent place on the agenda at each SMC meeting.

4. The Challenges

There were many reasons why it was going to be difficult to involve patients and the public in SMC decision-making. However, it was viewed an opportunity to find creative solutions and not a reason not to try. Examples of these challenges are shown below.

4.1 The Health Technology Board for Scotland (HTBS), now Quality Information for Scotland, and National Institute for Clinical Excellence (NICE) had developed strategies, but they did not have to operate within the very tight timescales of SMC. Whilst PAPIG could, and did, learn from these successful strategies they could not be applied as they stood.

4.2 As an aid to planning and resource allocation, SMC needs to be aware of what medicines may potentially be released onto the UK market as far ahead as possible and encourages pharmaceutical companies to submit information for consideration at an early point. This information is confidential and commercially sensitive. SMC has built a good relationship with the pharmaceutical industry, encouraging them to make submissions in a timely way. We had to be very careful not to damage this relationship.

4.3 There is an enormous volume of information involved in each submission to SMC from a pharmaceutical company and much of this information was commercially sensitive. This created considerable difficulties around confidentiality and how much, if any, of this information could be released outside of SMC.

4.4 Patients and the public in Scotland comprise a 5 million plus target audience for any information initiative. It was clear that in order to be active partners they would need information about SMC and how they could get involved but their pre-existing knowledge of medicines and their access to sources of information e.g. Internet, would be equally diverse.

4.5 Whilst an increasing number of patients are actively involved in decisions concerning their own healthcare, fewer members of the public become involved in policy level/strategic decisions. This may be through disinclination; through a belief that they do not know enough/have enough information to do so in a meaningful way; or through inadvertent creation of barriers to two-way communication. Whilst it would have been easier to create and use a small panel of patients/carers from across Scotland, PAPIG was keen to involve those who are usually silent and to create the *opportunity* for everyone rather than a few.

4.6 How could SMC gain a truly 'patient perspective'? Whilst having 2 lay members could offer two perspectives, unless these two members were very sick indeed they could not hope to offer a user perspective on every condition a medicines was intended to address! One option would have been to mimic the wider 'expert panel' i.e. medically qualified specialists who are not members of SMC but who can provide additional opinion if requested by New Drugs Committee (NDC) by establishing a panel of 'expert

patients': but would these individuals in any way be representative of the views of others? Michelle Childs, Consumers' Association, avers that, 'There is a need to clarify the purpose of representation and assess how best it can affect the consultation process'.

4.7 There have been concerns around the likelihood of any patient, or patient interest group, ever putting forward a case against the introduction of any new medicine that might conceivably benefit even one patient or carer? Added to this is the concern that patient interest groups are not privy to all the information available to SMC e.g. economic information provided by the pharmaceutical company and the economic analysis provided for the NDC by Pharmatrak and other health economists, all of whom are able to critique the economic modelling used and the factual basis thereof. Although patient interest groups are increasingly sophisticated in the abilities to critique complex research, including clinical trial outcomes, this is not universal whereas NDC members and those of its associated panel of experts are in a position to do this. This means that patient interest groups are continually producing their submissions on the basis of partial information.

4.8 Whilst the final outcome can be communicated to a patient interest group who has made a submission to SMC in respect of a particular medicine the only communication they receive after submission will be an acknowledgement and notification of outcome some weeks later. Developing a submission takes time and many patient interest groups operate with few employed staff. There may be a feeling that having gone to this effort something more than an outcome notification is needed. However, confidentiality prohibits discussion around why the decision was made as it was.

4.9 Initially, a number of patient interest groups were of the view that SMC, through PAPIG, should proactively seek information from them as and when a relevant medicine was due for review. This was problematic in that the task would have been delegated to SMC secretariat and their time was already fully occupied with other SMC work. In addition, it left SMC open to accusations of bias should it fail to notify a particular group either because they were unaware of their existence, despite an extensive database combining the then HTBS (now QIS) database and Voluntary Health Scotland database, or because it was not immediately apparent from their title that they might have an interest in that particular medicine.

4.10 SMC meets once a month and each agenda is full in order to meet the demands of our timescale for making recommendations on new medicines, new formulations and new indications. The increasing volume and pace of work consumes available secretariat time. Therefore, an administratively manageable strategy was required.

5. Involvement and Responsiveness

5.1 SMC receives from NDC their recommendations regarding whether a new medicine, new formulation or new indication should be recommended for general use within Scotland; recommended for restricted use i.e. patients who meet particular criteria only or prescription initiated by specialists only; or not recommended for use in Scotland. These recommendations are based upon clinical, economic and pharmacological data. What was missing was a patient/carer perspective.

5.2 Making decisions around clinical, economic, and pharmacological aspects of medicines is complex and involves teams whose expertise enables them to critically analyse information provided in a submission and, where appropriate, to draw on wider knowledge in order to determine the significance of any particular medicine within Scotland. Adding a patient/public perspective was important since it is those who suffer from the health problems who hold 'expert' status. Professor Julie Barlow, University of Coventry, states, 'Inevitably, patients can have greater insight into the psychological, functional and social consequences of their condition.'

5.3 By October 2002 PAPIG had developed a strategy that enabled members of the public to contribute to SMC decision-making using patient interest groups as the conduit. It would be unmanageable for reasons of time and administration to offer individual members of the public the opportunity to submit information therefore the strategy proposed that they could provide a relevant patient interest group with their individual contribution and that group could include it within a greater body of collated evidence submitted to SMC.

5.4 We have worked closely with a small number of patient interest groups in the design and development of both our strategy, supporting documents and processes for patient and public involvement. We have been able to make changes that are of benefit to both SMC and the public as a result of their valuable feedback. This lends support to the notion that resource-allocating decisions made by public bodies are more likely to lead to a better service, be more acceptable and lead to fewer complaints when these are reached with active involvement of the public at all key stages.

5.5 They have been 'kept in the loop' so-to-speak by further written communications informing them of progress that has been made.

6. Information:

It is impossible to be involved unless one is informed. Three types of information were needed:

6.1 Information about SMC and its processes

From the 2nd SMC meeting in Nov 2001 four SMC members including the two lay members began developing a Frequently Asked Questions Leaflet. It became clear that there was considerable ignorance around pharmaceuticals including their development, licence, marketing, prescribing (ignorance around Area Drug and Therapeutics Committees (ADTCs) and Health Board roles) and monitoring for safety. These could not all be addressed in one leaflet aimed at clarifying the role of SMC.

After several drafts the leaflet was finalised although some members of SMC were still making suggestions as to how it could be improved and what else was needed. It was piloted by the two lay members who used a questionnaire to sample the responses of members of the public and members of the voluntary health sector.

It was important to get this document into the public domain and so in July 02 the decision was made to 'go live' with it as it stood whilst acknowledge that this was an evolving process. Since this point only one addition has been made to the document and that pertaining to the process of public involvement. (see attached)

6.2 Information about the medicines that will be coming up for review and the outcomes of individual reviews.

Schedule of Work:

By December 02 SMC Website enabled members of the public to access its work schedule for the next 3 months. This opportunity had been held up for some time since there was concern on the part of one or two pharmaceutical companies. Their concern was due to a combination of commercial sensitivities and their code of practice in relation to how much information may be given to the public, how and when.

Following solicited feedback from users i.e. patient interest groups, the website schedule underwent a major revision in spring/summer 2003 making it more user-friendly. The site now shows medicines under categories e.g. respiratory conditions, circulatory conditions etc. together with the anticipated date on review by SMC. The new schedule site is a major improvement on its predecessor.

Once again, in response to feedback from users, we have introduced an email alert whereby they receive notification when any new medicine is placed on SMC work schedule, thus obviating their need to make frequent scouting visits to the site.

Information on the Medicine:

Once a patient interest group has identified a medicine that may be of interest to their members and others with similar health problems, there is a need to find out more detailed information on that medicine. The pharmaceutical company submission to SMC is strictly confidential but the Summary of Product Characteristics (SPC) that accompanies all licensed medicines is a public document once the product has received approval from the licensing authority - The Medicines and Healthcare Products Agency.

To complement this it has now been agreed that pharmaceutical companies may wish to submit a 'Patient Interest Group Summary' i.e. a lay version of their submission to SMC. This has presented various challenges not least of all being whether it complies with ABPI code of practice in respect of promoting medicines to the public.

In summer 2003 the 'SMC User Group Forum' agreed that this was a useful opportunity so long as it was closely monitored and not a compulsory activity. PAPIG has developed a cover-sheet for such summaries on which we make it clear that SMC does not endorse the information contained within it and that they should remember that it presents information from the perspective of one pharmaceutical company.

Submission deadline:

Patient interest groups can access the SPC via SMC secretariat who will also provide them with their submission deadline. This is important since their submission is copied to each SMC member and accompanies the pharmaceutical company submission and NDC recommendation that is distributed to members two weeks ahead of an SMC meeting.

Review outcome:

Patient interest groups would also wish to see the outcome of a review and this can be accessed through the same website. It is made clear that once a submission has been made no further communication can be entered into until the decision is put in the public domain. The information becomes public 4 - 5 weeks after the decision has been communicated to the pharmaceutical company, NHS Boards and their ADTCs. Following feedback from users it was agreed in August 03 that any patient interest group who making a submission will automatically receive the relevant SMC press release.

6.3 Information pertaining to how a submission can be made to SMC by a patient interest group.

A 'Guidance Document for Patient Interest Groups' explains the processes involved and is accompanied by a submission template. (see attached) Between September 2002 and July 2003 the document went through various modifications in the light of feedback from those who have/might use/d it.

We decided not to offer a 'model submission', either real or fictitious: it was felt that whilst the submission template provided a framework for submission there should be room for individual variation.

7. Building Capacity and Communications:

Our December meeting with 9 representatives from Patient Interest Groups i.e. Alzheimer Scotland Action on Dementia, Cystic Fibrosis Trust, National Asthma Campaign Scotland, Depression Alliance Scotland, Eczema Scotland, Roy Castle Lung Foundation, High Blood Pressure Foundation, Cancer Bacup and Mens Health Forum was primarily to ascertain their views on our proposals for involvement and how we could make this as user-friendly as possible. As a direct result of their feedback several modifications, as cited above, have been made.

Whilst PAPIG found the interactions both on the day and subsequently to be helpful it appeared that, despite the fact that many of them had well-established links with representatives from various pharmaceutical companies, they would value more information. PAPIG has planned a day-long event to be held on January 23rd at the Royal College of Physicians, Glasgow to address this need for information. The day will include talks on development of medicines; safety, quality and efficacy; pricing; SMC and how the public/patient interest groups can become involved. It will also explore how and why decisions are made at local level i.e. ADTC/Health Board regarding local access to medicines. It will include presentations from a users perspective in the form of patient interest groups who have made submissions to SMC.

8. Where next?

8.1 Recruiting and Training new members for SMC.

PAPIG has presented to SMC Senior Management Group a proposal for recruitment and training of new lay members. It is proposed that one new lay member is recruited to commence January 04 and that, by that point, PAPIG will have developed a training programme designed to enable new members to contribute meaningfully to SMC deliberations. It is our experience that lay members are sometimes left with little

preparation for their role on a committee and this diminishes the potentially valuable contribution they can make.

As an interim measure, and on the understanding that she may apply along with others for the lay membership position, we have asked another member of the public to join us between August 02 and January 04 and to help us develop a training programme that is truly responsive to the needs of a lay member.

8.2 Clear messages

There is evidence from patient interest groups of continuing confusion regarding the role of SMC in respect of so-called 'post-code prescribing'.

This issue has been evident from the outset and is reflected in various parliamentary questions. At its inaugural meeting SMO was described by Mac Armstrong, CMO, as creating a model for the rational introduction and use of new drugs into the Scottish healthcare system in a way which is consistent with evidence, equity and social justice. SMC was described as an advisory body, making recommendations and providing advice as to which drugs should be included in local drug formularies. The two key processes in introducing a new medicine are comparative efficacy (not addressed in licensing) and cost effectiveness.

SMC cannot, however, dictate to Health Boards and ADTCs how they will use their financial resources and it has always been stated that there must be room for local contextualisation/prioritisation and consequent development of local formularies.

This does not sit comfortably with recent statements from Labour and Liberal Democrats to the effect that, 'We will end postcode prescribing by ensuring drugs approved by NHS QIS are made available in each health board area'. This apparent conflict of information creates confusion for patient interest groups, patients and the public and is a continuing source of discontent.

8.3 Not the usual suspects!

The majority of Scotland's population would, if surveyed, not have heard of SMC despite the fact that they or those they care for are likely to be patients now or in the near future. It is often a much appreciated but small and unrepresentatively well-informed group of patient/public representatives who respond to consultation documents, participate in fora etc. PAPIG has expressed its intention to prepare a paper by December 03 suitable for publication in popular periodicals in order to raise the profile of SMC.

We must 'crack' the issue of providing information and opportunity for those who do not have regular access to the Internet.

8.4 What do we really want from Patient Interest Groups?

Some patient interest group submissions have been more informative to SMC's deliberations. A previous decision was made not to give feedback on individual submission but this prohibits a potential two-way learning opportunity. Therefore, we will be looking at how we can help patient interest groups make the most of this opportunity

which will be to the benefit of both their members/people with a similar health problem and to SMC.

8.5 Patient Interest Group Summaries

PAPIG will evaluate the impact and value of Patient Interest Group Summaries in June 04 to determine whether they increase the likelihood of submissions, how helpful they were and at what cost to the pharmaceutical industry.

8.6 Is the system user-friendly?

PAPIG will survey patient interest groups who have not made submissions with a view to ascertaining why this is and, where appropriate, modify processes and documentation in such a way as to encourage greater input.

9. Conclusions

The journey continues and the baton will be taken up by others as members of PAPIG and SMC retire and others take over. They will have new ideas and can build on work to date. It has been a slow process, some might say needlessly so at times, and so far there have been disappointingly few submissions from patient interest groups. We appear to have met all the criteria for good patient and public involvement; we have as open and transparent systems and procedures as possible within the constraints of confidentiality, so what more can we do or is the ball now firmly in their court?